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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/780,043

02/17/2004

Elizabeth Bates

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
2000 GALLOPING HILL ROAD
KENILWORTH, NJ 07033-0530

EXAMINER

DAHLE, CHUN WU

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

02/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/780,043

Applicant(s)

BATES ET AL.

Examiner

Chun Crowder

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 9, 17-23, 25-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 9, 17-23, 25-29, and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 31, 2007, has been entered.

2. Applicant's amendment to the claims, filed October 31, 2007, has been entered.

Claims 1-6, 8, 10-16, 24, and 30 have been canceled.

Claim 31 has been added.

Claims 7, 9, 17-23, 25-29, and 31 are pending and currently under consideration.

3. This Office Action is in response to Applicant's amendment to the claims and remarks filed on October 31, 2007.

The rejections of record can be found in the previous Office Actions, mailed on February 22, 2006, July 17, 2006, November 20, 2006, and August 9, 2007.

4. In light of applicant's amendment to the claims, the prior rejection, under 35 U.S.C. 112, 1st paragraph, new matter, has been withdrawn.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 20-23 and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

Applicant has claimed a pharmaceutical composition comprising an antibody or fragment thereof, wherein the antibody or fragment thereof binds an polypeptide consisting of amino acid sequence of SEQ ID NO:6 that is a product of activated monocytes.

The specification discloses that a gene isolated from human monocyte cell library and designated FDF03 encodes FDF3 protein with amino acid sequence of SEQ ID NO:2; a protein with amino acid sequence of SEQ ID NO:6 (designated as FDF03-S1) appears to be an activation isoform of FDF03 (e.g. see page 5 of the instant specification). Further, the specification discloses that FDF03-S1 is a type I transmembrane protein that belongs to the Ig superfamily and FDF03-S1 may associate with ITIM-bearing molecules (e.g. see page 7 of the instant specification). The specification further discloses that antibody specific for FDF03-S1 can be used to treat abnormal expression or abnormal signaling by a monocyte (e.g. see page 23).

However, the specification as filed does not provide sufficient enabling description of the claimed invention. A person skilled in the art is not enabled to use the claimed pharmaceutical composition comprising an antibody to SEQ ID NO:6 for the claimed intended uses.

It is noted that the recited “pharmaceutical composition” has the intended uses for prevention, diagnosis or treatment of diseases in human and animals. Thus, to enable such

claims, the specification must teach how to use the composition without undue experimentation for prevention, diagnosis, and treatment of diseases in human and animals. However, the instant specification fails to teach how to use a "pharmaceutical composition" as claimed. While the specification discloses that the antibody that binds SEQ ID NO:6 can be used for detection of activated monocyte, it is not apparent from the disclosure whether the protein level of FDF03-S1 (SEQ ID NO:6) is associated with any specific diseases. The specification does not provide any in vitro or in vivo experimental data to correlate the expression of SEQ ID NO:6 to any particular diseases. The uses of monoclonal antibodies in a pharmaceutical composition are unpredictable as evidenced by following reference: for example, Vitetta et al. (Science 2006 313:308-309) teach that given the complex structure of antibodies, designing therapeutic antibodies can be unpredictable; in the case of anti-CD28 antibody, healthy humans injected with the anti-CD28 antibody suffered immediate and profound side effects (see pages 308-309).

Therefore, it is unpredictable whether an antibody that binds SEQ ID NO:6 can be used as pharmaceutical composition for the intended uses for prevention, diagnosis or treatment of diseases in vivo since the biological role of SEQ ID NO:6 is not clear.

Given that the instant specification has not provided sufficient guidance and direction regarding the use of antibody specific to SEQ ID NO:6 in a pharmaceutical composition for the use of prevention, diagnosis or treatment of diseases in vivo, one of skill in the art would not be able to practice the claimed invention without undue experimentation.

In view of the quantity of experimentation necessary, the lack of working example for any uses of prevention, diagnosis or treatment of diseases in vivo, the unpredictability of the art, the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

7. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

The phrase “residues 195-205 of SEQ ID NO:6” is not supported by the original disclosure or claim as filed.

Applicant’s amendment, filed on October 31, 2007, directs the support to page 7, and asserts that since the full length of SEQ ID NO:6 is disclosed, the claimed “residues 195-205 of SEQ ID NO:6” is fully supported by the full length SEQ ID NO:6. This is not found persuasive for following reasons:

The specification as filed does not provide sufficient written description of the above-mentioned “limitation”. The specification does not provide sufficient support for an isolated antibody or fragment thereof that binds to “residues 195-205 of SEQ ID NO:6”. The specification only discloses antibody or antigen binding fragment thereof that binds full length SEQ ID NO:6; the instant claims now recite an antibody that binds “residues 195-205 of SEQ ID NO:6”, which were not clearly disclosed in the specification. Therefore, the claims represent a departure from the specification and claims originally filed. Applicant’s reliance on generic disclosure (antibody that binds to SEQ ID NO:6) does not provide sufficient direction and guidance to the features currently claimed (an isolated antibody or fragment thereof that binds to “residues 195-205 of SEQ ID NO:6”). It is noted that a generic or a sub-generic disclosure cannot support a species unless the species is specifically described. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679 683 (CCPA 1972) and MPEP 2163.05.

Such limitation recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 7, 9, 17-23, and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Adema et al. (WO 98/24906, cited in IDS filed 02/17/04) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586, reference listed on PTO-892 mailed on February 22, 2006) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886, reference listed on PTO-892 mailed on February 22, 2006) for reasons of record set forth in the previous Office Actions mailed on February 22, 2006, July 17, 2006, and November 20, 2006.

Given that applicant has canceled the new matter "but does not bind the polypeptide consisting of the amino acid sequence of SEQ ID NO:2" in amendment, filed on October 31, 2007, the withdrawn rejection has been reinstated herein.

Further, given that the claims have been accorded the priority of the applications 09/869,388 and PCT/US99/30004, which is 10/09/2001 and 12/29/1999, respectively, because the subject matter claimed in the instant application only has support under 35 U.S.C. 112 in priority applications 09/869,388 and PCT/US99/30004 but not in USSN 09/223,919, and 09/224,604. Specifically, insufficient support was identified for the limitation of "SEQ ID NOs: 6, 8, and 10" in USSNs 09/223,919 and 09/224,604. Thus, Adema et al. (WO 98/24906) is qualified as 102(b) type of prior art (see detailed analysis in previous Office Action mailed on February 22, 2006).

Adema et al. teach an isolated polypeptide of SEQ ID NO:2 isolated from monocyte wherein SEQ ID NO:2 is 80.4% identical to the claimed polypeptide of SEQ ID NO:6 (see attached sequence alignment). Adema et al. further teach methods of making and using monoclonal antibodies using polypeptide having amino acid sequences of SEQ ID NO:2 as immunogen using techniques such as hybridoma and recombinant technology. Furthermore, Adema et al. teach that the antibody can be fragment such as Fab, Fv, and can be attached to solid support including beads, and be included in units such as a kit (e.g. see pages 4-6). Moreover, Adema et al. teach that the antibody can be formulated into a pharmaceutical composition with pharmaceutically acceptable carriers and be presented in unit dosage form for parenteral administration, including subcutaneous administration and intravenous administration (e.g. see page 4 and 22-45).

As evidenced by Bost et al, antibodies can be specific and cross-react with the antigen. For example, antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., "Results, page 579).

As further evidenced by Bendayan, the specific reactivity of a monoclonal antibody can be highly specific yet cross-react with antigens from different species or even distinct proteins not related to the original antigen (page 886, last paragraph).

Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific. Therefore, the reference antibody to SEQ ID NO:2 is specific to the instant polypeptide with SEQ ID NO:6.

Applicant's arguments, filed on October 31, 2007, in conjunction with the Philips declaration under 37 C.F.R. 1.132 filed on May 21, 2007, have been fully considered but have not been found persuasive.

Applicant argues that the instant claims requires that the antibody specifically binds SEQ ID NO:6, said antibody would not bind other polypeptide even if there is significant overlapping amino acid sequences.

However, it is noted that there is no clear parameters have been laid in the instant specification for an antibody that "specifically bind" one antigen but not the other antigen. Given the high degree of sequence homology between the prior art polypeptide of SEQ ID NO:2 and instant SEQ ID NO:6, monoclonal antibody that binds to the prior art SEQ ID NO:2 would bind shared regions of sequence identity of the instant polypeptide of SEQ ID NO:6.

With respect to the Phillips Declaration, it is noted that Table I illustrated that antibodies made using extracellular domain of the FDF03-S1 (instant SEQ ID NO:6) that are homologous to FDF03 indeed cross react with FDF03 (instant SEQ ID NO:2) (e.g. see antibody MB 452-1F11 in Table I). While it is noted that antibodies (e.g. MB765-015) in Table 1 that is made using extracellular domain of the SEQ ID NO:2 do not bind SEQ ID NO:6, these species of antibodies does not provide sufficient support to show that the prior art antibody would not bind SEQ ID NO:6. All that is required to meet the claimed limitation is an antibody that specifically

binds SEQ ID NO:6. Given that the prior art antibody is made using polypeptide of SEQ ID NO:2 that is 80% identical to the instant SEQ ID NO:6, monoclonal antibody that binds the prior art SEQ ID NO:2 would bind shared regions of sequence identity of the instant polypeptide consisting of SEQ ID NO:6. As such, applicant's arguments and the Phillips declaration have not been found persuasive.

Therefore, the reference teachings anticipate the claimed invention.

10. Claims 7, 9, 17-23, and 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al. (US Patent Application 2005/0155089, reference on PTO-892 mailed on August 9, 2007) for reasons of record set forth in previous Office Action mailed on August 9, 2007) as evidenced by Campbell (Monoclonal Antibody Technology. 1985 Published by Elsevier Science Publishers. Chapter I, pages 1-32).

The previous Office Action mailed on August 9, 2007 states:

“Lal et al. teach human signal peptide containing proteins including proteins with amino acid sequence of SEQ ID NO:7 that is 100% identical to the instant SEQ ID NO:6 (see paragraph [0041] and attached sequence alignment, in particular). Lal et al. further teach purified antibodies that bind human signal peptide containing protein of SEQ ID NO:7 including monoclonal antibodies, antibody fragments such as Fab, Fv, recombinant antibody, e.g. humanized antibody or fragment thereof, and hybridoma that produces antibodies (see entire document, particular paragraphs [0074] and [0144]-[0153]). Furthermore, Lal et al. teach a pharmaceutical composition, comprising said antibodies and pharmaceutically acceptable carriers, suitable for parenteral administration including subcutaneous or intravenous administration (e.g. see paragraphs [0168]-[0183]).”

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that Lal et al. teach a polypeptide comprising SEQ ID NO:6 but Lal et al. do not teach an antibody that binds to a polypeptide consists of SEQ ID NO:6 wherein the

antibody recognizes monocyte cell. Further, applicant argues that Lal teach the sequences of 184 proteins but does not teach specific and substantial utility of those polypeptide; as such applicant asserts that one skill in the art would not have any motivation to make antibodies to those sequences. Therefore, applicant argues that Lal et al. is not enabled.

This is not found persuasive for following reasons:

In contrast to applicant's assertion that Lal et al. do not teach an antibody that binds a polypeptide consists of SEQ ID NO:7 (100% identical to the instant SEQ ID NO:6), it is noted that a prior art reference must be considered in its entirety, MPEP 2141.02. In this case, the reference, when considered in its entirety, clearly teaches antibody that binds polypeptide consist of SEQ ID NO:7 (e.g. see paragraph [0041]).

Further, in contrast to applicant's reliance recited limitation of "specifically recognizes monocyte cells", it is noted that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Here, given that the prior art antibody is made using polypeptide that is structurally identical to the instant SEQ ID NO:6 as antigen, the prior art antibody would inherently specifically recognize monocyte cells.

Furthermore, contrary to applicant's assertion that the prior art teachings are not enabled therefore cannot anticipate the claimed invention, the following is noted:

"The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102, however, differs from the enablement standard under section 112. In *In re Hafner*, 410 F.2d 1403 161 USPQ 783 (CCPA 1969), the court stated that "a disclosure lacking a teaching of how to use a fully disclosed compound for a specific, substantial

utility or of how to use for such purpose a compound produced by a fully disclosed process is, under the present state of the law, entirely adequate to anticipate a claim to either the product or the process and, at the same time, entirely inadequate to support the allowance of such a claim.” *Id.* at 1405; *see Schoenwald*, 964 F.2d at 1124; *In re Samour*, 571 F.2d 559, 563-64 197 USPQ 1 (CCPA 1978). The reason is that section 112 “provides that the specification must enable one skilled in the art to ‘use’ the invention whereas [section] 102 makes no such requirement as to an anticipatory disclosure.” *Hafner*, 410 F.2d at 1405; *see* 1 Donald S. Chisum, *Chisum on Patents* §3.04[1][c] (2002); *see also In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-52 64 USPQ2d 1202_ (Fed. Cir. 2001) (finding anticipation where applicant sought a patent based on a new use for a previously disclosed method).” Moreover, in order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. See MPEP 2122.

Here, given that the claimed antibody is enabled because the Lal et al. provide that SEQ ID NO:7 can be used as antigen to make antibody using well-known methods. Thus, the prior art antibody is enabled since the public is in possession of it.

Moreover, contrary to applicant's assertion that one of skill in the art would not be motivated to make antibody to the prior art SEQ ID NO:7, it is noted that the rejection is under 35 U.S.C. 102(e), not 103(a). Thus applicant's arguments regarding motivation to make antibody to the prior art polypeptide have not been found persuasive. Even if motivation were to be considered, it is noted that the methods of making antibody were well known and considered routine in the art at the time of invention. For example, Campbell teaches methods of making antibodies and the advantages of using antibodies e.g. monoclonal antibody in basic research, diagnostics and therapeutic uses (see entire document, particularly pages 2-23). Further, Campbell teaches that it is customary now for any group working on macromolecule to both clone the genes coding for it and make monoclonal antibodies to it, sometimes without a clear objective for their application (e.g. see page 28). In this case, Lal et al. clearly teach that polypeptides such as SEQ ID NO:7 is closely associated with proliferative cancerous tissues (e.g.

see paragraph [0139], in particular) and one of skilled in the art would have been motivated to make antibody to SEQ ID NO:7 that is 100% identical to the instant SEQ ID NO:6. Such antibody would meet the claimed limitation.

Therefore, applicant's arguments have not been found persuasive. Thus, the reference teachings anticipate the claimed invention.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lal et al. (US Patent Application 2005/0155089, reference on PTO-892 mailed on August 9, 2007) in view of Markussen (US Patent 5,317,092, reference on PTO-892 mailed on August 9, 2007) for reasons of record set forth in the previous Office action mailed on August 9, 2007.

The previous Office Action states:

"The teachings of Lal et al. have been discussed, supra, and teach that antibody binds human signal peptide containing protein with amino acid sequence of SEQ ID NO:7 can be used in various immunoassays such as ELISA (e.g. see paragraph [0154] and [0186])."

The reference teachings differ from the claimed invention by not describing an antibody or fragment thereof that is bound to a solid support.

Markussen teaches that antibodies immobilized to a solid support provide convenience for a method for isolating their target proteins or polypeptides in substantially pure form (see entire document, particularly column 2).

Therefore, it would have been obvious to the ordinary artisan at the time the invention was made to immobilize the antibody to a solid support.

The ordinary artisan would have been motivated to do so because antibodies immobilized to a solid support can be used in a convenient method for isolating their target proteins or polypeptides in substantially pure form.

Given the teachings of Lal et al. providing the uses of antibody in various immunoassays and the teachings of Markussen regarding method of using antibody immobilized to a solid support, the ordinary artisan at the time the invention was made would have had a reasonable expectation of success of producing the claimed antibody or fragment thereof that is bound to a solid support.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary."

Given the absence of additional rebuttal to the outstanding rejection of record in applicant's amendment, filed on October 31, 2007; the rejection has been maintained for the reasons of record.

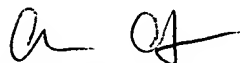
12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Eileen O'Hara can be reached 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Chun Crowder

Patent Examiner

February 3, 2008

Attachment: Amino acid sequence alignment of the prior art SEQ ID NO:2 of Adema et al. (WO 98/24906, cited in IDS filed 02/17/04) and the instant SEQ ID NO:6